K003622

DEC 1 8 2000

510(k) Summary.

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §.807.92.

1. The submitter of this premarket notification is:

Mike Hudon
Regulatory Approvals Engineer
Agilent Technologies
Patient Monitoring Division
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099
Tel.: (978) 659-3173
Fax.: (978) 687-2651

This summary was prepared on November 9, 1998.

2. The name of this device is the M2376A Device Link System. The common name is the HP Device Link. Current Classification is (74) Cardiovascular **MWI**, classification names for the externally connected devices are as follows:

REGULATION NUMBER	CLASSIFICATION NAME	PANEL	PROCODE
870.1110	Computer, blood pressure	Cardiovascular	74 DSK
870.1100	Alarm, blood pressure	Cardiovascular	74 DSJ
870.1130	System, measurement, blood pressure, noninvasive	Cardiovascular	74 DXN
870.2300	Monitor, cardiac	Cardiovascular	74 DRT
876.1800	Urinometer	Gastro-urology	78 EXS
876.5820	System, hemodialysis, access recirculation monitoring	Gastro-urology	78 MQS
880.5725	Pump, infusion	Gnr'l Hospital	80 FRN
870.3535	System, balloon, intra-aortic and control	Cardiovascular	74 DSP
868.5895	Continuous ventilator	Anesthesiology	73 CBK
868.1730	Computer, oxygen uptake	Anesthesiology	73 BZL
870.2700	Oximeter	Cardiovascular	74 DQA
868.1400	Carbon Dioxide Gas Analyzer	Anesthesiology	73 CCK
870.1915	Thermodilution probe	Cardiovascular	74QGL
868.2375	Breathing Frequency Monitor	Anesthesiology	73 BZQ

3. The M2376A Device Link System receives digital data produced by external devices through device specific cables, converts that data into the HL7 format and transmits that information to any networked Clinical Information System.

4. When connected to a bedside device, the M2376A Device Link System is intended for electronic data collection and clinical information management. Device Link is neither patient connected, nor does it remotely control the attached source device.

Declaration of Conformity with Design Controls

Verification and Validation Activities

To the best of my knowledge, the verification and validation activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Manufacturing Facility

The manufacturing facility, Agilent Technologies, Incorporated, Healthcare Solutions Group-Andover, Massachusetts, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Bob Hunt
Release Program Manager
Patient Monitoring Division
Healthcare Solutions Group
Agilent Technologies, Incorporated
Andover, Massachusetts 01810 USA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2000

Mr. Mike Hudon
Regulatory Approvals Engineer
Agilent Technologies, Inc.
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099

Re: K003622
M2376A Agilent Technologies Device Link System
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: November 22, 2000
Received: November 24, 2000

Dear Mr. Hudon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have

under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

510(k) Number (if known): _____

Device Name: M2376A Device Link System

Indications for Use:

The M2376A DeviceLink System is indicated for use in data collection and clinical information management either directly or through networks with independent bedside devices.

The M2376A is not intended for monitoring purposes, nor is the M2376A intended to control any of the clinical devices (independent bedside devices / information systems) it is connected to.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003622

Prescription Use ____X____ **OR** **Over-The-Counter Use _____**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)